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Serial No. 09/966,493 MCP-274

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Joseph Luber
Serial No.	:	09/966,493
Filed	:	9/28/2001
Title	:	IMMEDIATE RELEASE TABLET
Art Unit	:	1615
Examiner	:	Robert M. Joynes

Honorable Commissioner of Patents
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. §132

I, Joseph E. Luber, hereby declare:

1. I am a joint inventor of the subject matter of the above-identified application.

2. I have been employed by McNeil Consumer & Specialty Pharmaceuticals, division of McNeil-PPC, Inc., the assignee of this application, since 1990. My current position at McNeil is Principal Scientist, and I have held that position since 1998. From 1996 to 1998, I held the position of Senior Research Scientist. From 1991 to 1996, I held the position of Research Scientist. I hold a Bachelors degree in Chemistry from Penn State University.

3. I have reviewed US Patent No. 5,494,681 to Cuca et al., which relates to the use of melted wax in preparing a pharmaceutical delivery system.

4. I prepared a series of tablets containing 500 mg of acetaminophen as the active ingredient, 12 mg/tablet sodium starch glycolate, 0.5 mg/tablet colloidal silicon dioxide, 2 mg/tab magnesium stearate and wax. Four varieties of wax were used (Examples 1-4). The tablets were made as follows. The above ingredients were blended and compressed on a Manesty Betapress using 7/16" diameter, extra deep concave tooling. Following compression, a portion of the tablets were heated at 80° C for 30 minutes to melt the wax, and then allowed to cool to room temperature. Unheated tablets contained unmelted wax according to the invention.

5. Acetaminophen dissolution rates for the tablets were measured using the procedure of USP 26 under the Acetaminophen Tablet monograph, which uses pH 5.8 buffer in apparatus 2 at 50 rpm. The results are as follows:

Example	Contains	APAP Dissolution	
		Unheated	Heated
1	65 mg/tab Synthetic Wax X-2068 T20	15 min 101, 104, 105% 30 min 103, 104, 105%	12, 7, 7% 17, 13, 14%
2	60 mg/tab Sterotex K	15 min 97, 102, 101% 30 min 99, 104, 102%	10, 5, 5% 12, 7, 8%
3	60 mg/tab Mekon T60 Micro Wax	15 min 97, 102, 105% 30 min 99, 103, 105%	10, 5, 5% 13, 87, 8%
4	60 mg/tab Carnauba Wax	15 min 94, 99, 102% 30 min 99, 104, 103%	32, 34, 30% 77, 79, 73%

6. Tablets made with melted wax demonstrated markedly decreased dissolution of acetaminophen.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Sept 12, 2003
Date

Joseph R. Luber